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Patent

Case No.: 43305.12.0.43.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: ERIC C. LUO ET AL.

Application No.: 10/675,603

Group Art Unit: 1615

Filed: September 29, 2003

Examiner: Isis A.D. Ghali

Title: TRANSDERMAL AND TOPICAL ADMINISTRATION OF LOCAL ANESTHETIC AGENTS USING BASIC PERMEATION ENHANCERS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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December 29, 2006	
<i>12/29/06</i>	<i>Deborah M. Malay</i>
Date	Signature

**RESPONSE TO RESTRICTION REQUIREMENT**

This communication is filed in response to the office communication mailed August 29, 2006, the period for response to which has been extended to December 29, 2006 by the accompanying Petition and Fee for Extension of Time. In that office communication, the Examiner required the election of one group from among the following two invention groups:

- I. Claims 1-21, drawn to composition for enhanced delivery of local anesthetic, classified in class 424, subclass 449.
- II. Claims 22-42, drawn to a system for enhanced delivery of local anesthetic, classified in class 424, subclass 449, 448.

In response, Applicant provisionally elects claims 1-21 (Group I), with traverse. The Examiner simply asserts, though without explanation or support, that the composition of Group I, and the system of Group II, will have "different modes of operation based on their different designs". Putting aside the accuracy of this statement, the restriction requirement itself clearly fails to identify any of the categories, or in turn meet any of the criteria, required to demonstrate distinct inventions. See in particular MPEP 806.05. Absent this fundamental showing, the requirement itself is not proper and should be withdrawn.

The Action continues by stating two election of species requirements that pertain to Group I above, including as between the species identified in Claim 13 and 19, respectively. With regard to both election of species requirements, MPEP 802.02 provides that an election of species requirement is merely a type of restriction requirement, and hence again requires that a variety of criteria be met. However, the present Office Action fails to provide *any* basis at all for this requirement, and in turn, fails to meet *either* of the two fundamental requirements of *any* restriction requirement, as set forth in MPEP 808, namely, that it provide: (1) reasons why the inventions *as claimed* are either independent or distinct, and (2) reasons for insisting on restriction therebetween. Accordingly, the election of species requirement fails to meet the Office's own standards and should be withdrawn.

With regard to Claims 13, the Action asserts that this claim is generic to the following disclosed patentably distinct species:

- (a) Inorganic hydroxide;
- (b) Inorganic oxide; and
- (c) Inorganic salts of weak acids.

Applicant elects species (a) inorganic hydroxides, with traverse, and it would appear that all Claims 1-21 are readable thereon. The fact that the claimed chemical compounds may have different chemical structures and different actions does not, in and of itself, explain or rise to the level necessary to support an election requirement.

With regard to Claim 19, the Action asserts that this claim is generic to the following disclosed patentably distinct species:

- (a) Local anesthetic selected from procaine drugs including benzocaine, bupivacaine, chlorprocaine, cinchocaine, dexivacaine, diamocaine, dibucaine, etidocaine, hexylcaine, levobupivacaine, lidocaine, mepivacaine, oxethazaine, prilocaine, procaine, proparacaine, propoxycaine, pyrrocaine, risocaine, rodocaine, ropivacaine, tetracaine, and troclosan;
- (b) Benzyl benzoate;

- (c) Calamine;
- (d) Chloroxylenol;
- (e) Cocaine;
- (f) Dyclonine;
- (g) Ketamine;
- (h) Menthol;
- (i) Phenol;
- (j) Pramoxine;
- (k) Resorcinol; and
- (l) Troclosan.

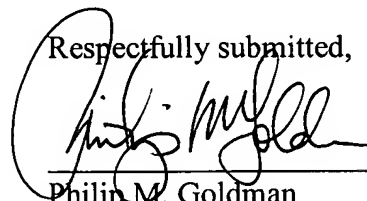
Applicant elects species (a) inorganic hydroxides, with traverse, and it would appear that remaining claims 1-21 are readable thereon. The fact that the claimed chemical compounds may have "different chemical structures and different modes of action" again does not itself explain or rise to the level necessary to support an election requirement.

To the contrary, the rules themselves provide (e.g., 37 CFR 1.141) that a reasonable number of species can indeed be included in a single application, where, as here, other conditions are met. Hence, reconsideration and withdrawal of both the restriction and election of species requirements, is respectfully requested.

Dated: \_\_\_\_\_

12/29/06

Respectfully submitted,



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